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MARK J. NUEL, PHD  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 GATEHOUSE ROAD  
SUITE 100 EAST  
P.O. BOX 747  
FALLS CHURCH, VIRGINIA 22040-0747

In re Application of :  
Ge Ruowen et al :  
Serial No.: 09/766,412 : PETITION DECISION  
Filed: January 22, 2001 :  
Attorney Docket No.: 1781-0215P :

This letter is in response to the Petition under 37 C.F.R. 1.144, and 1.181 filed on November 15, 2005, to review the restriction requirement and withdraw Finality of the last Office action.

**BACKGROUND**

A review of the file history shows that this application was filed under 35 U.S.C. 111 and that the Office set forth a restriction requirement under 35 U.S.C. 121, of claims 1-24 in an office action mailed June 4, 2004. The groupings are reproduced below:

Group I, claims 1-18, drawn to a peptide and pharmaceutical composition thereof;

Group II, claims 19-21, drawn to a method for preventing or treating undesired angiogenesis by administering the peptide formulation of Group I;

Group III, claims 22-24, drawn to a method for preventing or treating primary tumor growth or metastasis by administering the peptide formulation of Group I.

The Examiner supported this restriction between the peptide and pharmaceutical composition thereof, method for preventing or treating undesired angiogenesis by administering the peptide formulation of Group I and method for preventing or treating primary tumor growth or metastasis by administering the peptide formulation of Group I with appropriate reasoning.

The examiner then stated that Groups II and III are distinct inventions because, "...the different inventions use different methods of treatment."

The examiner also set forth a sequence election requirement stating that the multiple SEQ ID NOS represent sequences which are considered to be patentably distinct compounds. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore, a further restriction is applied to each sequence.

Applicants elected group I, claims 1-18 and SEQ ID NO: 30 with traverse in the response filed on September 25, 2003.

The examiner addressed applicants' traversal of the restriction requirement by first confirming that applicant elected Group I and SEQ ID NO: 30. The examiner noted that applicants had amended the claims to provide for a method for preventing or treating undesired angiogenesis (Group II) and a method for preventing or treating primary tumor growth or metastasis of Group III along with the peptide of Group I by amending the claims to read as methods for preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis by administering the compound of Group I. As such, the examiner explained, the method of treating tumor growth appears to be a species of the method for preventing undesired angiogenesis. The examiner also stated that the sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore, a further restriction is applied to each sequence. Thus, all SEQ ID NOS's other than SEQ ID NO: 30 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. The examiner then revised the restriction requirement in view of applicant's amendments and sent out the following new restriction requirement to replace the former one on February 20, 2004:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 1-8, 13, 14, 19, 22, and 25-28, drawn to a plasminogen, pharmaceutical composition thereof and to a method for preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis;

Group II, claims 1-8, 13, 14, 19, 22, and 25-28, drawn to endostatin, pharmaceutical composition thereof and to a method for preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis;

Group III, claims 1-8, 13, 14, 19, 22, and 25-28, drawn to vascular endothelial growth factor (VEGF), pharmaceutical composition thereof and to a method for preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis;

Group IV, claims 1-8, 13, 14, 19, 22, and 25-28, drawn to KDR/FLK-1 receptor protein, pharmaceutical composition thereof and to a method for preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis;

The examiner stated that the groups were unrelated since the compounds/compositions are not connected in design, operation or effect.

Applicants responded to the new requirement by electing Group II, with traverse. The traversal was on the grounds that the inventions of Groups I-IV as disclosed and claimed in this application would most efficiently be examined together. Applicants stated that since claims 9, 10, 15, 16, 20 and 23 were not restricted out that it was presumed that these claims would be examined along with Group II.

The examiner mailed a non-final office action to applicants on June 4, 2004, stating that the election of Group II was acknowledged and that although the compositions/compounds of Groups I-IV are used as pharmaceutical formulations for the same method of preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis, the compositions/compounds have different sources, structures resulting in different functions and different effects. The examiner in response to the applicants' remarks about claims 9, 10, 15, 16, 20 and 23 being examined along with Group II stated that SEQ ID NO: 30 will be examined and that all other SEQ ID NOs other than SEQ ID NO:30 are withdrawn from further consideration.

Applicants noted in their response to the above action that they elected SEQ ID NO:30 and that all of the claims (1,2,6-8, 10, 13-16, 19, 20, 22, 23, 25-29) all read on or relate to the elected species.

The examiner in an Office action mailed November 17, 2004, stated that claims 10, 15, 16, 20 and 23 are withdrawn as non-elected inventions. The examiner advised applicants to cancel these claims and then indicated that claims 1, 2, 6-8, 13, 14, 19, 25-27, and 29 were allowable.

Applicants in the next response indicated that each of claims 10, 15, 16, 20, 23 depends from allowed claim 1. Applicants then argued that since claim 1 is allowable the examiner must examine other species that are embraced by the generic claim, which includes the allowable sequence (SEQ ID NO :30).

In the Office action mailed April 8, 2005, the examiner indicated that claims 10, 15, 16, 20 and 23 are withdrawn as directed to a non-elected invention for the reasons of record. Next the examiner stated that the allowed claims were now no longer allowable due to non-compliance with 35 U.S.C. 112, first paragraph.

Applicants in response to the above action indicated that claims 1, 2, 6-8, 10, 13-16, 19, 20, 22, 23 and 25-29 all read on or relate to the elected sequence. The outstanding Office action indicated that claims 10, 15, 16, 20 and 23 were withdrawn from consideration. Applicants had elected SEQ ID NO: 30 which is recited in claim 25. Claim 25 depends from claim 10. In other words, claim 10 and claims 15, 16, 20 and 23 dependent thereon include the elected sequence. Applicants also added new claims 30-32 directed to SEQ ID NOS: 29, 31 and 32.

In the Final Office action mailed November 21, 2005, the examiner again asserted that claims 10, 15, 16, 20, 23, 25-28 and new claims 30-32 were withdrawn from further consideration. The examiner stated that new claims 30-32 were withdrawn because they were not in the original claims and that this was a case of election by original presentation since SEQ ID NOS: 29, 31 and 32 were originally non-elected. The examiner addressed applicants' argument that this was

not an election of species but a restriction limited to the SEQ ID NO: 30 and that applicants never challenged it in the previous Office actions.

This petition to review the finality of the restriction requirement and Finality of the Office action mailed September 21, 2005, was filed on November 15, 2005.

## DISCUSSION

The application, file history and petition have been considered carefully. In the Petition, Applicants request consideration of claims 10, 15, 16, 25 and 26 along with the other claims currently being examined.

Applicants also petition to withdraw the Final Office action of September 21, 2005 and to receive an Office action on the merits of claims 10, 15, 16, 25 and 26 along with the other claims being examined on their merits in this application. Applicants argue that under the Administrative Act they should have the other claims examined along with the claims of Group II examined. Applicants argue that it is a fact that the peptide having the amino acid sequence of SEQ ID NO: 30 which the examiner acknowledges is the elected sequence is a peptide which is a portion of an endostatin protein that has a length (13 amino acids) within the claim 1 range of 7 to 20 amino acids. The examiner is examining claim 1 ("A peptide comprising a portion of an endostatin protein, wherein said peptide is of length from 7-20 amino acids long") and claim 7 ("The peptide of claim 1 that has a length of 9 to 20 amino acids"). Applicant further argues that those peptides have lengths respectively of 13, 14, and 16 amino acids. It is not clear why the examiner is refusing to examine claim 25. If claim 23 were to be stated in the manner of claim 7, claim 25 would read "The peptide of claim 1 that has a length of 13 amino acids". Applicants then refer to 37 CFR 1.142 to support that claim 10 is not independent from claim 1 and that claim 10 expressly depends from claim 1. Applicants ask if the examiner were to find a reference which disclosed the subject matter of claim 25, would the examiner allow claim 1 as being drawn to subject matter which is patentably distinct from the subject matter disclosed in claim 25? Applicants therefore, conclude, that the restriction is improper.

Applicants are correct that the examiner has failed to apply a proper standard for restriction in this case. The examiner has failed to establish why claims 10, 15, 16, 25 and 26 were withdrawn from consideration. The reason for withdrawing these claims is incorrect. The claims do encompass applicants' claimed SEQ ID NO: 30 as argued. The examiner improperly omitted these claims from examination as they clearly encompass the elected sequence. The examiner clearly considered SEQ ID NO: 30 and it is not clear why the examiner excluded these claims.

The examiner was correct in stating that this is a restriction requirement for the sequence and **not** an election of species as applicant argued and the examiner was correct in stating that applicant never challenged the restriction to SEQ ID NO: 30.

Nevertheless, the applicant is still correct in that the withdrawn claims 10, 15, 16, 25 and 26 do contain the SEQ ID NO: 30 and thus should and will be re-joined with the elected group II claims.

For these reasons, claims 10, 15, 16, 25 and 26 will be rejoined with claims 1, 2, 6-8, 13, 14, 19, 22 and 29. The previous Office action is withdrawn as incomplete and a new office action considering claims 1, 2, 6-8, 10, 13-16, 19, 22, 25, 26, and 29 will be issued.

## **DECISION**

The petition under 37 CFR 1.144 and 1.181 is **GRANTED** for the reasons set forth above.

**Claims 10, 15, 16, 25 and 26 are rejoined with claims 1, 2, 6-8, 13, 14, 19, 22 and 29. The application will be forwarded to the examiner for preparation of a new Office action consistent with this petition decision. Applicants need not reply to the Office action mailed September 21, 2005, which has been withdrawn.**

Should there be any questions regarding this decision, please contact Special Program Examiner William Dixon, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-0519 or by Official Fax at 571-273-8300



Bruce M. Kisliuk  
Director, Technology Center 1600